REMARKS

In the Office Action dated April 24, 2008, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I Claims 1-20, in part, drawn to a method of genotype comprising RNA or DNA from connexion 26.

Group II Claims 1-20, in part, drawn to a method of genotype comprising RNA or DNA from pendrin.

Group III Claims 1-20, in part, drawn to a method of genotype comprising RNA or DNA from mitochondrial 12s rRNA.

Group IV Claims 1-20 in part, drawn to a method of genotyping comprising RNA or DNA from usherin.

Group V Claims 21-25, drawn to a set of one or more oligonucleotides and a kit.

Further, the Examiner states that if one of Groups I-IV is elected, Applicants must further elect a specific sequence from SEQ ID NOS: 1-64.

Claims

Applicants first respectfully submit that there were 23 claims pending before the Examiner issued the Restriction Requirement. There were 25 claims filed in the PCT application originally. However, the claim pages were amended during the international phase of the PCT application. The amended claims include claims 1-17 and 20-25 (a total of 23 claims). A courtesy copy of the PCT application, including the amended claim pages, was provided to the Office when the present application entered the U.S. national phase on May 18, 2005. Apparently, the Examiner's Restriction Requirement is directed to claims 1-25 originally filed in the PCT application, rather than the 23 claims that were pending in the present application.

By way of the foregoing amendments, Applicants have amended the pending 23 claims, by renumbering claims 20-25 as claims 18-23, and have added new claims 24-25. No new matter is introduced.

Election

In order to be fully responsive to the Examiner's Requirement for Restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I (corresponding to claims 1-17 above), in part, drawn to a method of genotype comprising RNA or DNA from connexion 26. Applicants further provisionally elect SEQ ID NO: 1 as the elected sequence for continued prosecution.

Moreover, Applicants have added new claims 24-25, directed to a method of genotyping a subject based on contacting a panel of allele specific oligonucleotides covering "a mutation in *each* of the genes connexion 26, pendrin, mitochondrial 12s rRNA and usherin". Claim 25 specifically defines the panel of allele specific oligonucleotides as comprising SEQ ID NO: 1 (which covers the mutation 35W18A in connexion 26). Applicants respectfully submit that to the extent that new claims 24-25 read on genotyping at least connexion 26 and SEQ ID NO: 1, these claims should be included in the examination.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

The Examiner alleges that the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. Specifically, the Examiner contends that the technical feature, which is shared by Groups I-V, is a genotyping

method to detect deafness mutations. The Examiner is of the opinion that Groups I-V do not share a special technical feature over the art because Hone et al. (*Otolarynogology Clinics of North America* Vol 35 p. 751, 2002) teach a genotyping method to detect deafness mutations of connexin. Therefore, the Examiner concludes that a genotyping method to detect deafness mutations fails to make a contribution over the prior art; and thus there is no special technical feature that links Groups I-V.

Moreover, the Examiner has required to further elect a specific SEQ ID NO. from SEQ ID NO: 1-64 if one of Groups I-IV is elected. The Examiner contends that a specific gene and specific combinations of genes are separate inventive concepts. The Examiner states that the description fails to disclose that all of the genes in each of the combinations share a common property or activity. According to the Examiner, while each combination of genes might serve to detect its own respective full length DNA(s), due to the lack of sequence homology between the genes, one gene cannot be used to amplify the same region of DNA of another gene.

In the first instance, Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on the evaluation of novelty or unobviousness based on the prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue on merits during prosecution whether the claims are patentable over the prior art. Restriction of the claims at this stage would deny Applicants such an opportunity.

Further, Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a

single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.) In the present case, the listed groups of invention are linked together by the single inventive concept that a genotyping method of a relevant pathological condition is achieved by employing at least one allele specific oligonucleotide which covers a mutation selected from connexion 26, pendrin, mitochondrial 12s rRNA or usherin.

Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from another other, as presented by the Examiner.

Accordingly, it is respectfully submitted that the present claims, including new claims 24-25, satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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